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| APPLICATION NO.    | F             | ILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------|---------------|--------------|----------------------|---------------------|------------------|
| 09/990,673         |               | 11/13/2001   | Sujatha Karoor       | DI-5666             | 2485             |
| 29200              | 7590          | 11/25/2005   |                      | EXAMINER            |                  |
| BAXTER I           | <b>IEALTH</b> | CARE CORPORA | BOUCHELLE, LAURA A   |                     |                  |
| 1 BAXTER<br>DF2-2E | PARKWA        | AY           | ART UNIT             | PAPER NUMBER        |                  |
| DEERFIELI          | O, IL 60      | 015          | 3763                 |                     |                  |

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary   |   | Application No.  | Applicant(s)   |  |  |  |  |  |
|---|---|--|--|--|--|--|--|--|
|   |   | 09/990,673 KAROOR ET AL.   |  |  |  |  |  |  |
|   |   | Examiner   | Art Unit   |  |  |  |  |  |
|   |   | Laura A. Bouchelle   | 3763   |  |  |  |  |  |
| The MAILING D. Period for Reply   | ATE of this communication ap  | pears on the cover sheet with the c  | correspondence address   |  |  |  |  |  |
| WHICHEVER IS LONG - Extensions of time may be aw<br>after SIX (6) MONTHS from the set of th | GER, FROM THE MAILING Described aliable under the provisions of 37 CFR 1. The mailing date of this communication. The mailing date of this communication, after above, the maximum statutory period or extended period for reply will, by statutice later than three months after the mailing | LY IS SET TO EXPIRE 3 MONTH( DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from the, cause the application to become ABANDONE and date of this communication, even if timely filed | N .<br>nely filed<br>the mailing date of this communication.<br>D (35 U.S.C. § 133). |  |  |  |  |  |
| Status  |   |  |  |  |  |  |  |  |
| 1) Responsive to co   | ommunication(s) filed on 03 /   | November 2005.   |  |  |  |  |  |  |
| 2a) ☐ This action is FII  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |  |  |  |
| ·— · · ·  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |  |  |  |  |  |  |
| closed in accord  | ance with the practice under  | Ex parte Quayle, 1935 C.D. 11, 45  | 53 O.G. 213.   |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-58</u> is/  | are pending in the application  | n.   |  |  |  |  |  |  |
| ·   | 4a) Of the above claim(s) 12-58 is/are withdrawn from consideration.  |  |  |  |  |  |  |  |
| ·= · · · ·  | Claim(s) is/are allowed.  |  |  |  |  |  |  |  |
|   | Claim(s) <u>1-11</u> is/are rejected.   |  |  |  |  |  |  |  |
| 7) Claim(s)   | is/are objected to.<br>are subject to restriction and/  | or election requirement  |  |  |  |  |  |  |
|   | are subject to restriction and  | or election requirement.   |  |  |  |  |  |  |
| Application Papers  |   |  |  |  |  |  |  |  |
| ,   | is objected to by the Examin  |  |  |  |  |  |  |  |
| 10) $\boxtimes$ The drawing(s) filed on <u>03 April 2002</u> is/are: a) $\boxtimes$ accepted or b) $\square$ objected to by the Examiner.   |   |  |  |  |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |  |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |  |  |  |  |  |  |  |
| TT) The bath of decis   | aration is objected to by the E   | Examiner. Note the attached Office   | Action of form 1 10-132.   |  |  |  |  |  |
| Priority under 35 U.S.C.  | § 119   |  |  |  |  |  |  |  |
| a) All b) Som  1. Certified of  2. Certified of  3. Copies of   | ne * c) None of: copies of the priority document copies of the priority document the certified copies of the priority   | nts have been received in Applicat<br>ority documents have been receive  | ion No   |  |  |  |  |  |
| • •   | n from the International Burea<br>detailed Office action for a lis  | au (PC) Rule 17.2(a)). It of the certified copies not receive  | ed.  |  |  |  |  |  |
| occ the attached  | detailed Office detion for a no   | to the certified depice het receive  |  |  |  |  |  |  |
| Attachment(s)   |   |  |  |  |  |  |  |  |
| 1) Notice of References Cite 2) Notice of Draftsperson's P  | d (PTO-892)<br>Patent Drawing Review (PTO-948)  | 4) Interview Summary Paper No(s)/Mail D  |  |  |  |  |  |  |
|   | atement(s) (PTO-1449 or PTO/SB/08   |  | Patent Application (PTO-152)   |  |  |  |  |  |

## DETAILED ACTION

## Election/Restrictions

1. Claim 12-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups II-VI, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 11/3/2005.

## Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1, 4, 5, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al (US 5944684) in view of Henne et al (US 4610794). Roberts discloses a system for continuous renal function replacements comprising a body 11 and inlet and an outlet defining an interior (See Fig. 2), the interior comprising a layer of urease, a layer of zirconium oxide, a layer of zirconium phosphate, and a layer of carbon (Col. 8, lines 30-34).
- 4. Claim 1 differs from Roberts in calling for the fluid to contact the zirconium phosphate before contacting the urease or zirconium oxide layers. However, applicant's specification gives this limitation no criticality, as it discloses the layers in a variety of orientations. Henne teaches

a dialysis membrane comprising absorbents such as active carbon, zirconium oxide, zirconium phosphate, and urease, that can be used in any combination, in the same layer or in separate layers, one under the other using appropriate amounts for best results (Col. 12, lines 43-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the layers of Roberts such that the fluid passes through the zirconium phosphate layer before the urease or zirconium oxide layer as taught by Henne to get the best results.

- 5. Claim 8 differs from Roberts in calling for two layers of zirconium phosphate, and claim 9 calls for two layers of zirconium oxide. Henne teaches that the layers can be in any configuration that provides the best filtration of the fluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the layers of Roberts to have two layers of zirconium phosphate or zirconium oxide as taught by Henne to provide the best filtration of the fluid.
- 6. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marantz et al (US 3669880) in view of Henne et al. Marantz discloses a dialysis system comprising a body with an inlet and an outlet with an interior comprising zirconium phosphate, urease, carbon and hydrous zirconium oxide that has the nitrate ion removed (Col. 4, line 67 Col. 5, line 10).
- 7. Marantz lacks the limitation of claim 1 calling for the fluid to contact the zirconium phosphate before the urease or zirconium oxide. Therefore, claims 2 and 3, depending from claim 1, differ from Marantz in calling for the fluid to contact the zirconium phosphate before

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the urease or zirconium oxide. Henne teaches a dialysis membrane comprising absorbents such

as active carbon, zirconium oxide, zirconium phosphate, and urease, that can be used in any

combination, in the same layer or in separate layers, one under the other using appropriate

amounts for best results (Col. 12, lines 43-55). Therefore, it would have been obvious to one of

ordinary skill in the art at the time of invention to make the layers of Roberts such that the fluid

passes through the zirconium phosphate layer before the urease or zirconium oxide layer as

taught by Henne to get the best results.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al in 8.

view of Henne et al as applied to claim 1 above, and further in view of Wong (US 6627164).

Claim 6 differs from the teachings of Roberts in view of Henne in calling for the zirconium

phosphate to have a pH of approximately 2 to 8. Wong teaches the use of zirconium phosphate at

a pH of about 5 to 6 so that it can be dried to form a free flowing powered (Col. 3, lines 34-42).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention

to modify the zirconium phosphate of Roberts in view of Henne to have a pH of approximately

2-8 as taught by Wong so that the zirconium phosphate can be dried to form a free flowing

powder.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al in

view of Henne et al as applied to claim 1 above, and further in view of Matsui et al (US

4659744). Claim 7 differs from the teachings of Roberts in view of Henne in calling for the

zirconium oxide to have a pH of 6-13. Matsui teaches the use of Zirconium oxide at a pH of

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greater than 6 because at pH 6 and above zirconium oxide acts as a cation exchanger (Col. 1, lines 39-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the zirconium oxide of Roberts in view of Henne to have a pH of 6-13 as

taught by Matsui so that it will act as a cation exchanger.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marantz in view of Henne et al. Marantz discloses a dialysis system comprising an inlet and an outlet with an interior in between, where in the inlet and the outlet comprise a header 23. See Fig. 2. The device further comprises a layer of urea, a layer of zirconium phosphate, a layer of zirconium phosphate, and a layer of carbon. See Abstract. Henne teaches a dialysis membrane comprising absorbents such as active carbon, zirconium oxide, zirconium phosphate, and urease, that can be used in any combination, in the same layer or in separate layers, one under the other using appropriate amounts for best results (Col. 12, lines 43-55). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the layers of Marantz such that the fluid passes through the zirconium phosphate layer before the urease or zirconium oxide layer as taught by Henne to get the best results.

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al in view of Henne et al as applied to claim1 above, and further in view of Rosa et al (US 5618441). Claim 11 differs from the teachings of Roberts in view of Henne in calling for an opening for venting. Rosa teaches a dialysis machine comprising a vent to selectively vent accumulated air from the chamber (Col. 7, lines 8-12). Therefore, it would have been obvious to one of ordinary

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skill in the art at the time of invention to modify the teachings of Roberts in view of Henne to

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include a vent as taught by Rosa to vent accumulated from the chamber.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125.

The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

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system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NICHOLAS D. LUCCHESI TECHNOLOGY CENTER 3700 Laura A Bouchelle Examiner Art Unit 3763

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